

JAN 28 2004

K040060

510(K) SUMMARY

Sonoline G50™ and Sonoline G60 S™ Diagnostic Ultrasound Systems

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of a 510(k) Summary.

1. Submitted By:

Siemens Medical Solutions USA, Inc., Ultrasound Division
22010 S.E. 51st Street
Issaquah, WA 98029

Contact Person:

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Regulatory Affairs

Phone: (425) 557-1825

FAX: (425) 391-9198

Date Prepared:

November 25, 2003

2. Proprietary Name:

SONOLINE G50™ Ultrasound System and SONOLINE G60 S™ Ultrasound System

Common/ Usual Name:

Diagnostic Ultrasound System with Accessories

Classification Name:

21 CFR 892.1550

Ultrasonic Pulsed Doppler Imaging System	FR # 892.1550	Product Code 90-IYN
Ultrasonic Pulsed Echo Imaging System	FR # 892.1560	Product Code 90-IYO
Diagnostic Ultrasound Transducer	FR # 892.1570	Product Code 90-ITX

3. Predicate Device:

K020353, 2/13/2002, SONOLINE G50 and SONOLINE G60 S.
K032111, 7/18/2003, ACUSON CV70 Cardiovascular System
K003525, 11/22/2000, Medison Voluson 730
K003125, 10/20/2000, SONOLINE Elegra (with Axis™ Automated OB Calipers and 3D measurements)

4. Device Description:

The G50/G60 S are general purpose, mobile, software-controlled, diagnostic ultrasound systems with on-screen displays for thermal and mechanical indices related to potential bioeffect mechanisms. Their function is to acquire primary or secondary harmonic ultrasound echo data and display it in: B-Mode, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Amplitude Doppler Mode, a combination of modes, or Harmonic Imaging, or 3D/4D imaging, on a CRT display.

The G50/G60 S have been designed to meet the following product safety standards:

- UL 2601-1, Safety Requirements for Medical Equipment
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment

- AIUM/NEMA UD-3, 1998 Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, 1998 Acoustic Output Measurement Standard for Diagnostic Ultrasound
- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
 - EN/IEC 60601-1
 - EN/IEC 60601-1-1
 - EN/IEC 60601-1-2
- IEC 1157 Declaration of Acoustic Power
- ISO 10993 Biocompatibility

5. Intended Uses:

The G50/G60 S ultrasound imaging systems are intended for the following applications: General Radiology, Abdominal, Intraoperative, Small Parts, Transcranial, OB/GYN, Cardiac, Pelvic, Neonatal/Adult Cephalic, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

6. Technological Comparison to Predicate Device:

The SONOLINE G50/G60 S are substantially equivalent to the SONOLINE G50 & G60 S, cleared via K020353; SONOLINE CV70, cleared via K032111; SONOLINE Elegra with Axis OB Calipers, cleared via K003125; and Medison Voluson 730, cleared via K003525. All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures and flow, and calculations.

End of 510(k) Summary



JAN 28 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Siemens Medical Solutions USA, Inc.
Ultrasound Group
% Mr. Mark Job
Responsible Third Party
Regulatory Technology Service, LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K040060

Trade Name: SONOLINE G50/G60 S Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging systems
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 IYN, IYO, and ITX
Dated: January 9, 2004
Received: January 13, 2004

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SONOLINE G50/G60 S Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

C5-2 Convex Array

C6-2 Convex Array

C8-5 Convex Array
5.0C50+ Convex Array
C6-3 3D Mechanically Driven 3D Convex Array
EV9-4 Convex Array Endovaginal
Endo-VII Mechanical Sector Endovaginal
Endo-V 3D Mechanical Sector Endovaginal
EC9-4 Convex Array Endovaginal
BE9-4 Convex Array Endocavity
5.0L45 Linear Array
7.5L70 Linear Array
LB5-2 Linear Array
L10-5 Linear Array
VF13-5 Linear Array
VF13-5SP Linear Array
7.5L50I Linear Array
7.5L50Q Linear Array
LAP8-4 Laparoscopic
P4-2 Phased Sector Array
5.0P10 Phased Sector Array
MPT7-4 Phased Sector Array Tee
CW2 Continuous Wave Doppler
CW5 Continuous Wave Doppler

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

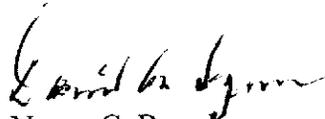
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,


for

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): ~~K020060~~ (SONOLINE G50/G60 S Family)

Device Name: **SONOLINE G50/G60 S Diagnostic Ultrasound Systems**

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

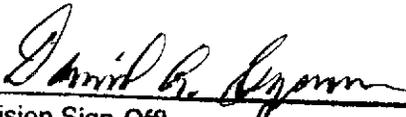
Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5
Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,4,5
Intraoperative (Note 6)		P	P	P		P	P		BMDC	Note 3
Intraoperative Neurological		P	P	P		P	P		BMDC	Note 3
Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5
Small Organ (Note 1)		P	P	P	P	P	P		BMDC	Note 2,3,4,5
Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 3
Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2
Cardiac		P	P	P	P	P	P		BMDC	Note 2,7
Transesophageal		P	P	P	E	P	P		BMDC	Note 2,3,7
Transrectal		P	P	P		P	P		BMDC	Note 2,3,4,5
Transvaginal		P	P	P		P	P		BMDC	Note 2,3,4,5
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5
Laparoscopic		P	P	P		P	P		BMDC	Note 3
Musculo-skeletal Conventional		P	P	P	P	P	P		BMDC	Note 2,3,4,5
Musculo-skeletal Superficial		P	P	P	P	P	P		BMDC	Note 2,3,4,5
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K020060

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): ~~4020058~~ (SONOLINE G50/G60 S Family)

Device Name: **C5-2 Convex Array Transducer for use with:
 SONOLINE G50/G60 S Diagnostic Ultrasound Systems**

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

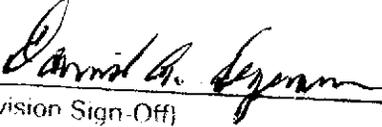
Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K040060

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): ~~K020058~~ (SONOLINE G50/G60 S Family)

Device Name: **C6-2 Convex Array Transducer for use with:
 SONOLINE G50/G60 S Diagnostic Ultrasound Systems**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Daniel A. Rejman
 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K040060

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): ~~K020000~~ (SONOLINE G50/G60 S Family)

Device Name: **C8-5 Convex Array Transducer for use with:
 SONOLINE G50/G60 S Diagnostic Ultrasound Systems**

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		P	P	P		P	P		BMDC	Note 3,4,5
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 3,4,5
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 3,4,5
Neonatal Cephalic		P	P	P		P	P		BMDC	Note 3,4,5
Adult Cephalic										
Cardiac		E	E	E		E	E		BMDC	Note 3,4,5,7
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 3,4,5
Musculo-skeletal Superficial		E	E	E		E	E		BMDC	Note 3,4,5
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
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- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging

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Prescription Use (Per 21 CFR 801.109)

David A. Seymour
 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K020000

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): ~~K000112, K000000~~ (SONOLINE G50/G60 S Family)

Device Name: **5.0C50+ Convex Array Transducer for use with:
 SONOLINE G50/G60 S Diagnostic Ultrasound Systems**

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

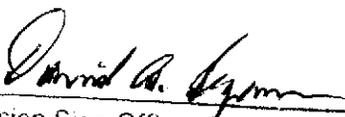
Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	Note 3,4,5
Abdominal		P	P	P	P	P	P		BMDC	Note 3,4,5
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		BMDC	Note 3,4,5
Small Organ (Note 1)		P	P	P	P	P	P		BMDC	Note 3,4,5
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		BMDC	Note 3,4,5
Laparoscopic										
Musculo-skeletal Conventional		E	E	E	E	E	E		BMDC	Note 3,4,5
Musculo-skeletal Superficial		E	E	E	E	E	E		BMDC	Note 3,4,5
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging

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Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K040060

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): ~~K020050~~ (SONOLINE G50/G60 S Family)

Device Name: **C6-3 3D Mechanically Driven 3D Convex Array Transducer for use with:
 SONOLINE G50/G60 S Diagnostic Ultrasound Systems**

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

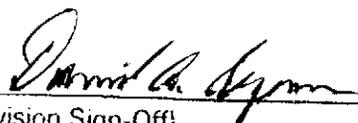
Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5
Small Organ (Note 1)										
Neonatal Cephalic		E	E	E		E	E		BMDC	Note 2,3,4,5
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
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Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K040060

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): ~~K020000~~ (SONOLINE G50/G60 S Family)

Device Name: **EV9-4 Convex Array Endovaginal Transducer for use with:
 SONOLINE G50/G60 S Diagnostic Ultrasound Systems**

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

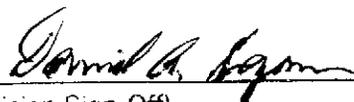
Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N	N	N		N	N		BMDC(N)	Note 2,3,4,5
Transvaginal		P	P	P		P	P		BMDC	Note 2,3,4,5
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)



(Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K040060

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): ~~R020050~~ (SONOLINE G50/G60 S Family)

Device Name: **Endo-VII Mechanical Sector Endovaginal Transducer for use with:
 SONOLINE G50/G60 S Diagnostic Ultrasound Systems**

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P						BM	Note 3
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)										
Neonatal Cephalic		P	P						BM	Note 3
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		P	P						BM	Note 3
Transvaginal		P	P						BM	Note 3
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

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Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number R040060

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): ~~K020050~~ (SONOLINE G50/G60 S Family)

Device Name: **Endo-V 3D Mechanical Sector Endovaginal Transducer for use with:
 SONOLINE G50/G60 S Diagnostic Ultrasound Systems**

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

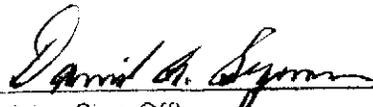
Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P						BM	Note 3
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)										
Neonatal Cephalic		N	N						BM(N)	Note 3
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N	N						BM(N)	Note 3
Transvaginal		P	P						BM	Note 3
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K040060

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): ~~K020000~~ (SONOLINE G50/G60 S Family)

Device Name: **EC9-4 Convex Array Endovaginal Transducer for use with:
 SONOLINE G50/G60 S Diagnostic Ultrasound Systems**

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

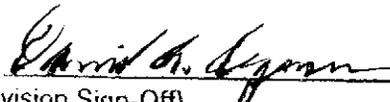
Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		P	P	P		P	P		BMDC	Note 2,3,4,5
Transvaginal		P	P	P		P	P		BMDC	Note 2,3,4,5
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K040060

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K

Device Name: **BE9-4 Convex Array Endocavity Transducer for use with:
 SONOLINE G50/G60 S Diagnostic Ultrasound Systems**
 Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

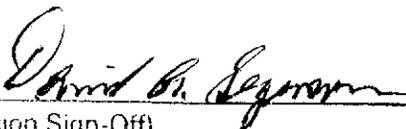
Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		N	N	N		N	N		BMDC(N)	Note 2,3,4,5
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N	N	N		N	N		BMDC(N)	Note 2,3,4,5
Transvaginal		N	N	N		N	N		BMDC(N)	Note 2,3,4,5
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging

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Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K040060

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): ~~K020110, K020112, K020050~~ (SONOLINE G50/G60 S Family)

Device Name: **5.0L45 Linear Array Transducer for use with:
 SONOLINE G50/G60 S Diagnostic Ultrasound Systems**

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

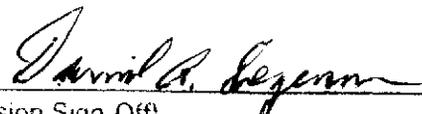
Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,4,5
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N		BMDC(N)	Note 2,3,4,5
Small Organ (Note 1)		P	P	P	P	P	P		BMDC	Note 2,3,4,5
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5
Laparoscopic										
Musculo-skeletal Conventional		P	P	P	P	P	P		BMDC	Note 2,3,4,5
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K040060

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): ~~K020058~~ (SONOLINE G50/G60 S Family)

Device Name: **7.5L70 Linear Array Transducer for use with:
 SONOLINE G50/G60 S Diagnostic Ultrasound Systems**

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

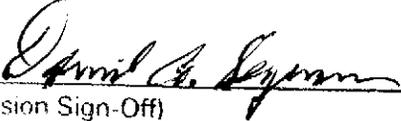
Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 3,4,5
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 3,4,5
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		E	E	E		E	E		BMDC	Note 3,4,5
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 3,4,5
Musculo-skeletal Superficial		P	P	P		P	P		BMDC	Note 3,4,5
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K040060

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): ~~K020050~~ (SONOLINE G50/G60 S Family)

Device Name: **LB5-2** Linear Array Transducer for use with:
SONOLINE G50/G60 S Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

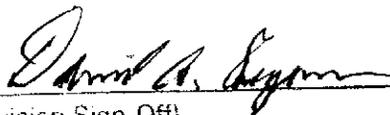
Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 4,5
Abdominal		P	P	P		P	P		BMDC	Note 4,5
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K040060

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): ~~K020555~~ (SONOLINE G50/G60 S Family)

Device Name: **L10-5 Linear Array Transducer for use with:
 SONOLINE G50/G60 S Diagnostic Ultrasound Systems**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5
Neonatal Cephalic		N	N	N		N	N		BMDC(N)	Note 2,3,4,5
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5
Musculo-skeletal Superficial		P	P	P		P	P		BMDC	Note 2,3,4,5
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Rejman
 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K040060

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): ~~K040060~~ (SONOLINE G50/G60 S Family)

Device Name: **VF13-5 Linear Array Transducer for use with:
 SONOLINE G50/G60 S Diagnostic Ultrasound Systems**

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

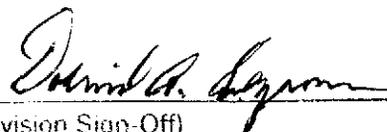
Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		BMDC	Note 3,4,5
Small Organ (Note 1)		P	P	P	P	P	P		BMDC	Note 3,4,5
Neonatal Cephalic		N	N	N	N	N	N		BMDC(N)	Note 3,4,5
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		BMDC	Note 3,4,5
Laparoscopic										
Musculo-skeletal Conventional		P	P	P	P	P	P		BMDC	Note 3,4,5
Musculo-skeletal Superficial		P	P	P	P	P	P		BMDC	Note 3,4,5
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)



(Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K040060

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): ~~K020000~~ (SONOLINE G50/G60 S Family)

Device Name: **VF13-5SP Linear Array Transducer for use with:
 SONOLINE G50/G60 S Diagnostic Ultrasound Systems**

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (note 6)		P	P	P		P	P		BMDC	Note 3,4,5
Intraoperative Neurological		P	P	P		P	P		BMDC	Note 3,4,5
Pediatric		P	P	P		P	P		BMDC	Note 3,4,5
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 3,4,5
Neonatal Cephalic		N	N	N		N	N		BMDC(N)	Note 3,4,5
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 3,4,5
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 3,4,5
Musculo-skeletal Superficial		P	P	P		P	P		BMDC	Note 3,4,5
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Repman
 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K040060

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): ~~R002142, R020000~~ (SONOLINE G50/G60 S Family)

Device Name: **7.5L50I Linear Array Transducer for use with:
 SONOLINE G50/G60 S Diagnostic Ultrasound Systems**

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		P	P	P		P	P		BMDC	Note 3,4,5
Intraoperative (Note 6)		P	P	P		P	P		BMDC	Note 3,4,5
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 3,4,5
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 3,4,5
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 3,4,5
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Johnson

(Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number

 R040060

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): ~~K062142, K020333~~ (SONOLINE G50/G60 S Family)

Device Name: **7.5L50Q** Linear Array Transducer for use with:
SONOLINE G50/G60 S Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

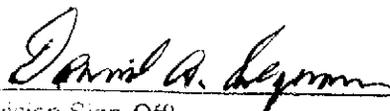
Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		P	P	P		P	P		BMDC	Note 3,4,5
Intraoperative (Note 6)		P	P	P		P	P		BMDC	Note 3,4,5
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 3,4,5
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 3,4,5
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 3,4,5
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K040060

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): ~~K000000~~ (SONOLINE G50/G60 S Family)

Device Name: **LAP8-4** Laparoscopic Transducer for use with:
SONOLINE G50/G60 S Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

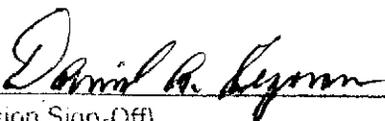
Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Note 6)		P	P	P		P	P		BMDC	Note 3,4,5
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic		P	P	P		P	P		BMDC	Note 3,4,5
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K040060

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): ~~K020555~~ (SONOLINE G50/G60 S Family)

Device Name: **P4-2 Phased Sector Array Transducer for use with:
 SONOLINE G50/G60 S Diagnostic Ultrasound Systems**

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

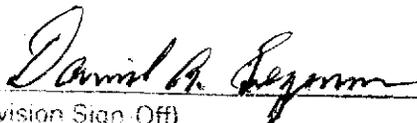
Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		N	N	N	N	N	N		BMDC(N)	
Abdominal		P	P	P	P	P	P		BMDC	Note 2,3
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N		BMDC(N)	
Small Organ										
Neonatal Cephalic										
Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2,3
Cardiac		P	P	P	P	P	P		BMDC	Note 2,3,7
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K040060

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): ~~K002142, K002000~~ (SONOLINE G50/G60 S Family)

Device Name: **5.0P10** Phased Sector Array Transducer for use with:
SONOLINE G50/G60 S Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	Note 2
Abdominal		P	P	P	P	P	P		BMDC	Note 2
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		BMDC	Note 2
Small Organ										
Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2
Adult Cephalic										
Cardiac		P	P	P	P	P	P		BMDC	Note 2,7
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040060

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): ~~K020000~~ (SONOLINE G50/G60 S Family)
~~K070707~~ (Sequoia) (Transducer cleared as TE-V5M)

Device Name: **MPT7-4 Phased Sector Array TEE Transducer for use with:
 SONOLINE G50/G60 S Diagnostic Ultrasound Systems**

Intended Use: **Ultrasound imaging or fluid flow analysis of the human body as follows:**

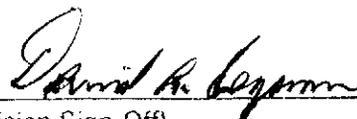
Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal		P	P	P	P	P	P		BMDC	Note 2,3,7
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging

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Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K040060

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): ~~K020000~~ (SONOLINE G50/G60 S Family)

Device Name: **CW2 Continuous Wave Doppler Transducer for use with:
 SONOLINE G50/G60 S Diagnostic Ultrasound Systems**

Intended Use: **Ultrasound imaging or fluid flow analysis of the human body as follows:**

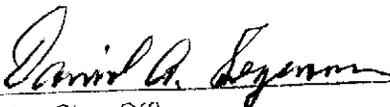
Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac					P					
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging

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Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K040060

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): ~~K020058~~ (SONOLINE G50/G60 S Family)

Device Name: **CW5** Continuous Wave Doppler Transducer for use with:
SONOLINE G50/G60 S Diagnostic Ultrasound Systems

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

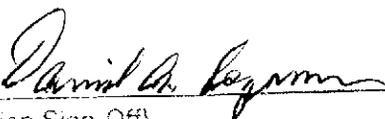
Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel					P					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging

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Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K040060